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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,931	12/27/2001	Vera Mahler	0273-0007	7190

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EXAMINER

NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/026,931	Applicant(s) MAHLER ET AL.	
	Examiner Patrick J. Nolan	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-48 is/are pending in the application.
- 4a) Of the above claim(s) 24-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2-18-05</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. Newly added claims 24-48 are pending. Claims 12-23 were cancelled.
2. Newly submitted claims 24-32 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the method of making the allergen is patentably distinct from the method of use of said allergen because of the different steps the recited with different endpoints.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 24-32 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 33-40 and 43-48 stand rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication 2004/0091500 A1, of record, for reasons set forth in the Office Action mailed 10-4-04.

Applicant's arguments filed 2-18-05 have been fully considered but are not found persuasive.

Applicant argues the mechanism of action behind the currently recited claims differs from the prior art. In essence the current invention is drawn to inducing blocking antibodies while the prior art is drawn to creating allergen derivatives that have reduced IgE binding.

However, the claims are not drawn to inducing blocking antibodies, they are drawn to methods of treatment by administering an allergen derivative that either induces IgG antibodies

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or wherein the allergen derivative has decreased IgE binding as compared to the naturally occurring allergen. As readily acknowledged by Applicant's representative "Paragraph 0046 mentions that the theory of the alleged prior art is supported by observations that levels of specific IgE are unaffected by successful vaccination treatment, and that successful treatment is often accompanied by a substantial rise in allergen specific IgG4". The prior art teaches administering an allergen derivative that induces production of IgG antibodies. The claims are not drawn to inducing IgG antibodies all the time, the fact that the prior art does often is enough to anticipate the claimed invention because the claim is not drawn to treating a population of people but to a single individual, as such, in the prior art persons whose IgG antibodies were induced by the treatment method anticipates the claimed invention. It is noted that claims 34-37 were included in the rejection, since the prior art treatment method did not affect the level of IgE in people allergic to the wild type allergen. This fact clearly indicates the allergen derivative had no IgE binding capacity since a hallmark of repeated allergen exposure is dramatic increases in IgE levels due to IgE binding ability of the wild type allergen leading to increases in Mast cell sensitization and degranulation which leads to increases in IL-4 production and B cell switching from IgG production to IgE production. In other words if the allergen derivative had any IgE binding capacity it would lead to increased levels of IgE upon administration.

The following new ground of rejection is necessitated by Applicant's amendment filed 2-18-05.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 35-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The newly added claim language drawn to 10% or 5% or elimination of IgE binding has no support in the originally filed specification or claims.

7. Claims 41-42 are objected to because of the following informalities: They appear to be exact duplicates. The only difference between the two claims is the use of the being in claim 41 versus is in claim 42. Appropriate correction or clarification is required.

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: There is no support in the originally filed specification for the term at least 100 ug in claim 45. It was found in original claim 7, but not in the specification.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.



Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

May 14, 2005